STATUTORY INSTRUMENTS

# 1977 No. 1056

# MEDICINES

## The Medicines (Fees) Amendment Regulations 1977

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| *Made* - - - | 24 *June* 1977 |
| *Laid before Parliament* | 24 *June* 1977 |
| *Coming into Operation* | 15 *July* 1977 |

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, with the consent of the Treasury, in exercise of powers conferred by section 1(1) and (2) of the Medicines Act 1971**(a)** and now vested in them**(b)** and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the following regulations, hereby make the following regulations:—

*Citation, commencement and interpretation*

**1.**—(1) These regulations may be cited as the Medicines (Fees) Amendment Regulations 1977 and shall come into operation on 15th July 1977.

(2) These regulations shall be read as one with the Medicines (Fees) Regulations 1976**(c)** as amended **(d)**, (hereinafter referred to as "the principal regulations").

*Amendment of regulation 1 of the principal regulations*

**2.** In regulation 1(2) of the principal regulations (definitions) after the definition of "calendar year" there shall be inserted the following definitions:—

""imported proprietary product" means a proprietary medicinal product imported other than from a member State of the European Economic Community;

"proprietary medicinal product" means

(*a*) a ready-prepared medicinal product placed on the market in the United Kingdom under a special name and in a special pack,

(*b*) for the purposes of paragraph (*a*) "medicinal product" does not include—

(i) vaccines, toxins or serums,

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**(a)** 1971 c.69.

**(b)** In the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c.36), and section 1(3) of, and paragraph 2(1)(*b*) of Schedule 1 to, the Northern Ireland Act 1974 (c.28).

**(c)** S.I. 1976/347 (1976 I, p.968).

**(d)** S.I. 1976/1145 (1976 II, p.3123).

(ii) medicinal products based on human blood or blood constituents or radioactive isotopes,

(iii) homoeopathic medicinal products, or

(iv) veterinary drugs;";

"Standard Provisions Regulations" means the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971**(a)**, as amended **(b)**;".

*Amendment of regulation* 5 *of the principal regulations*

**3.** In paragraph (3) of regulation 5 of the principal regulations for "or 6" there shall be substituted "6 or 7".

*Amendment of regulation* 6 *of the principal regulations*

**4.**—(1) After paragraph (6) of regulation 6 of the principal regulations (fees in respect of variations) there shall be inserted the following paragraph—

"(6A) If an application is for the variation of a wholesale dealer's licence which is or is to be subject to the provisions of paragraph 8 of Schedule 3 to the Standard Provisions Regulations ("qualified person"), and the variation relates to—

(*a*) anything done or to be done in relation to an imported proprietary product, or

(*b*) naming in the licence the person who is to act as a qualified person

there shall be payable by the applicant a variation fee equal to the amount shown in paragraph 7 of column 2 of Part I of Schedule 1.".

(2) In paragraph (7) of regulation 6 after the words "product licence" there shall be inserted the words "or wholesale dealer's licence in the circumstances in which paragraph (6A) of this regulation applies".

*Amendment of Schedule* 1 *to the principal regulations*

**5.**—(1) Part I of Schedule 1 to the principal regulations (Fees) shall be amended in accordance with the following paragraph and shall accordingly have effect as set out in the Schedule to these regulations.

(2) In Part I of Schedule 1—

(*a*) at the end of paragraph 6 of column 1 there shall be inserted the words "not being a licence to which the following paragraph applies";

(*b*) after paragraph 6 of column 1 there shall be inserted the following paragraph—

"7. Wholesale dealer's licence which relates to imported proprietary products and is subject to the provisions of paragraph 8 of Schedule 3 to the Standard Provisions Regulations";

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**(a)** S.I. 1971/972 (1971 II, p.2809).

**(b)** The relevant amending instruments are S.I. 1972/1226, 1977/1053 (1972 II, p.3708; 1977 II, p. 2996).

(*c*) after paragraph 6 of column 2 there shall be inserted the following paragraph—

"7. £50 for each separate set of premises in which any functions specified in paragraph 8(3) of Schedule 3 to the Standard Provisions Regulations are to be carried out in relation to imported proprietary products to which the licence relates, or £10 for each separate set of premises in which medicinal products to which the licence relates are or are to be stored, whichever amount is the greater.";

(*d*) after paragraph 6 of column 3 there shall be inserted the following paragraph—

"7. The amount specified in paragraph 7 of column 2, or an amount calculated in accordance with Parts IV, V and VI of this Schedule, whichever is the greater, except in relation to an application to which paragraph 1 or 2 of Part VII of this Schedule applies.".

(3) In Part V of Schedule 1—

(*a*) after paragraph 4 there shall be inserted the following paragraph—

"4A. For the purpose of calculating annual fees for wholesale dealer's licences to which paragraph 7 of column 1 of Part 1 of this Schedule applies "turnover" means the gross value at the prices paid by the applicant for imported proprietary products, except imported proprietary products which are in the possession of, or are handled by, the applicant in such circumstances as are mentioned in paragraph 8(7) or paragraph 8(8) of Schedule 3 to the Standard Provisions Regulations, which are distributed by him during the calendar year which ends 20 months before the end of a licence year.";

(*b*) in paragraph 6 for "and 4" there shall be substituted "4 and 4A";

(*c*) after paragraph 6 there shall be inserted the following paragraph—

"7. The provisions of paragraph 6 of this Part of this Schedule shall apply in relation to wholesale dealer's licences to which paragraph 4A of this Part of this Schedule applies as if in paragraph 6 any references to the gross value of sales were references to the gross value at the prices paid by the applicant for imported proprietary products.".

(4) In Part VI of Schedule 1—

(*a*) in the heading of Table 3 after the words "MANUFACTURER'S LICENCES" there shall be inserted the words "AND WHOLESALE DEALER'S LICENCES";

(*b*) for paragraph 2(iii) there shall be substituted the following:—

"(iii) where the licence is a manufacturer's licence the sum of £10,000 together with £2,000 in respect of each set of premises in which manufacture or assembly is carried on, or";

(*c*) after paragraph 2(iii) there shall be inserted the following:—

"(iv) where the licence is a wholesale dealer's licence to which paragraph 7 of column 1 of Part 1 of this Schedule applies, the sum of £10,000 together with £2,000 in respect of each set of

premises in which any functions specified in paragraph 8(3) of Schedule 3 to the Standard Provisions Regulations are to be carried out in relation to imported proprietary products to which the licence relates.".

*David Ennals,*
Secretary of State for Social Services.

13th June 1977.

*John Morris,*
Secretary of State for Wales.

14th June 1977.

*Bruce Millan,*
Secretary of State for Scotland.

16th June 1977.

In Witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 17th June 1977.

(L.S.)

*John Silkin,*
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 20th day of June 1977.

(L.S.)

*N. Dugdale,*
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 21st day of June 1977.

(L.S.)

*J.A. Young,*
Permanent Secretary.

We consent.

*T.E. Graham,*
*J. Dormand,*
Two of the Lords Commissioners of Her Majesty's Treasury.

24th June 1977.

## SCHEDULE

Regulation 5(1)

CONTAINING PART I OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS AS AMENDED BY THESE REGULATIONS **(a)**

### PART I

### FEES

| Column 1<br>Kind of licence or certificate | Column 2<br>Initial Fee | Column 3<br>Annual Fees |
|---|---|---|
| 1. Product licence (products for human use) | 1. (*a*) £1,800, or<br>(*b*) £60, if the product to which the application relates is a product specified in Part II or satisfies the conditions of Part III of this Schedule. (Subject to the provisions of paragraph 3 of Part VII of this Schedule) | 1. £50, or an amount calculated in accordance with Parts IV, V and VI of this Schedule, whichever is the greater, except in relation to an application to which paragraphs 1 or 2 of Part VII of this Schedule applies. |
| 2. Product licence (products for veterinary use) | 2. (*a*) £1,800, or<br>(*b*) £60, if the product to which the application relates is a product specified in Part II or satisfies the conditions of Part III of this Schedule. (Subject to the provisions of paragraph 3 of Part VII of this Schedule) | 2. £50, or an amount calculated in accordance with Parts IV, V and VI of this Schedule, whichever is the greater, except in relation to an application to which paragraphs 1 or 2 of Part VII of this Schedule applies. |
| 3. Clinical trial certificate | 3. £50, except in relation to an application to which paragraph 4 of Part VII of this Schedule applies. | 3. Nil. |
| 4. Animal test certificate | 4. £50, except in relation to an application to which paragraph 5 of Part VII of this Schedule applies. | 4. Nil. |
| 5. Manufacturer's licence | 5. (*a*) £100 for each set of premises in which manufacturing operations are to be carried out | 5. The amounts specified in paragraphs 5(*a*) (*b*) and (*c*) of column 2, or an amount |

**(a)** The additions made by these regulations are shown in italics.

| Column 1<br>Kind of licence or certificate | Column 2<br>Initial Fee | Column 3<br>Annual Fees |
|---|---|---|
| | under the terms of the licence, and<br>(*b*) £50 for each set of premises in which assembly (but not manufacturing) operations are to be carried out under the terms of the licence, and<br>(*c*) £10 for each set of premises in which medicinal products are to be stored for distribution under the terms of the licence. (Subject to the provisions of paragraph 3 of Part VII of this Schedule) | calculated in accordance with Parts IV, V and VI of this Schedule, whichever is the greater, except in relation to an application to which paragraphs 1, 2 or 6 of Part VII of this Schedule applies. |
| 6. Wholesale dealer's licence *not being a licence to which the following paragraph applies* | 6. £10 for each separate set of premises in which medicinal products to which the licence relates are or are to be stored. | 6. £10 for each separate set of premises in which medicinal products to which the licence relates are or are to be stored. |
| 7. *Wholesale dealer's licence which relates to imported proprietary products and is subject to the provisions of paragraph 8 of Schedule 3 to the Standard Provisions Regulations* | 7. *£50 for each separate set of premises in which any functions specified in paragraph 8(3) of Schedule 3 to the Standard Provisions Regulations are to be carried out in relation to imported proprietary products to which the licence relates or £10 for each separate set of premises in which medicinal products to which the licence relates are or are to be stored, whichever amount is the greater.* | 7. *The amount specified in paragraph 7 of column 2, or an amount calculated in accordance with Parts IV, V and VI of this Schedule, whichever is the greater, except in relation to an application to which paragraph (1) or (2) of Part VII of this Schedule applies.* |

## EXPLANATORY NOTE

*(This Note is not part of the Regulations.)*

These Regulations further amend the Medicines (Fees) Regulations 1976. The main changes are—

(*a*) a new paragraph is inserted in regulation 6 of the principal regulations relating to the fees payable on applications for variation of certain wholesale dealer's licences;

(*b*) new paragraphs are added to Part I of Schedule 1 to the principal regulations specifying initial and annual fees in respect of certain wholesale dealer's licences; and

(*c*) new paragraphs are inserted in Parts I, V and VI of Schedule 1 relating to the calculation of annual fees in respect of those licences.

The other amendments are of a minor or consequential nature.

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